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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/415,540	10/08/99	HAWKINS	P PF-0148-2-DI
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HM12/0116

Legal Department
Incyte Pharmaceuticals, Inc.
3160 Porter Drive
Palo Alto CA 94304

EXAMINER

SLOBODYANSKY, E

ART UNIT	PAPER NUMBER
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1652
DATE MAILED:

20
01/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/415,540

Applicant(s)
Hawkins et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Jan 9, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 18-22 is/are pending in the application.

Of the above, claim(s) 1 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 18-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Continued Prosecution Application

The request filed on January 9, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/415,540 is acceptable and a CPA has been established. An action on the CPA follows.

The preliminary amendment filed January 9, 2001 amending claim 19 has been entered.

Claims 1 and 18-22 are pending. The prosecution is being continued on the invention elected and prosecuted by Applicants in the prior application, see Office action mailed May 31, 2000.

Claims 18- 22 are under examination, claim 1 is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19, with dependent claims 18 and 20-22, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

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that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 recites "a naturally-occurring human polynucleotide sequence variant encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1".

With regard to a naturally-occurring human polynucleotide sequence variant, there is no description of any mutational site that exist in nature, and there is no description of how the structure of SEQ ID NO:2 relates to the structure of any allele including strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would not conclude that applicant was in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claims.

Claims 18 and 20-22 are drawn to a method of use of a vast diverse genus of a probe comprising 15, 30 or 60 nucleotides of SEQ ID NO:2. This genus includes DNAs encoding many structurally and functionally unrelated proteins.

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The specification does not disclose structural, physico-chemical or biological characteristics of a polypeptide encoded by a DNA comprising 15, 30 or 60 nucleotides of SEQ ID NO:2. The specification does not teach correlation between the structure and the function of the genus. Therefore, based on the instant disclosure, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of a DNA comprising 15, 30 or 60 nucleotides of SEQ ID NO:2. Therefore, a naturally-occurring DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 and a method of use of a probe comprising 15, 30 or 60 nucleotides of SEQ ID NO:2 lack sufficient written description needed to practice the invention of claims 18 and 20-22.

Claims 18 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of use of a fragment of SEQ ID NO:2 or a fragment of a DNA encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1, said fragment consisting of at least 15, 30 or 60 nucleotides, does not reasonably provide enablement for a method of use of a probe comprising at least 15, 30 or 60 nucleotides of SEQ ID NO:2 or a sequence encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1. The specification does not enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988).

They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not support the broad scope of the claim which encompass all modifications and fragments of any sequence that comprises a fragment of SEQ ID NO:2 because the specification does not establish: (a) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide encoded by a DNA of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement.

The state of the art does not allow the predictability of the properties based on the structure. The properties of a polypeptide of an unknown length and structure are unpredictable based on a fragment. Therefore, one skilled in the art would require guidance as to how to use a probe comprising 15, 30 or 60 nucleotides of SEQ ID NO:2 or a sequence encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1 wherein said probe is not a fragment of said sequences in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

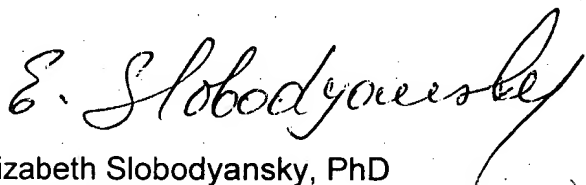
The rejection of claims 18-22 under 35 U.S.C. 102(b) over Yang et al. made in the Office action mailed May 31, 2000 is withdrawn because there is no indication that the sequence identical to the bovine sequence of Yang et al. naturally occurs in humans.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in dark ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

January 11, 2001